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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
|---|-------------|----------------------|---------------------|------------------|--|
| 10/596,520  | 04/21/2008  | Theresa M. Reineke   | 91830.0542769       | 7539             |  |
| 24256 7550 08/31/2010<br>DINSMORE & SHOHL LLP<br>1900 CHEMED CENTER |             |                      | EXAMINER            |                  |  |
|   |             |                      | SCHULTZ, JAMES      |                  |  |
| 255 EAST FIF<br>CINCINNATI  |             |                      | ART UNIT            | PAPER NUMBER     |  |
| ca (ca a arra,  |             |                      | 1633                |                  |  |
|   |             |                      |                     |                  |  |
|   |             |                      | MAIL DATE           | DELIVERY MODE    |  |
|   |             |                      | 08/31/2010          | PAPER            |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/596,520 REINEKE ET AL. Office Action Summary Examiner Art Unit

| · · · · · · · · · · · · · · · · · · ·   | LAUIIIIICI  | ALC OILL   |              |  |  |  |
|---|---|--|--------------|--|--|--|
|   | James (Doug) Schultz, PhD   | 1633   |              |  |  |  |
| - The MAILING DATE of this communication appears on the cover sheet with the correspondence address   |   |  |              |  |  |  |
| Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DV Extensions of time may be available under the provisions of 37 CFR 1.1 after SNI, (6) MONTHS from the mailing date of the communication If NO period for reply with the second of the communication of | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N.<br>nely filed<br>the mailing date of this o<br>D (35 U.S.C. § 133). |              |  |  |  |
| Status  |   |  |              |  |  |  |
| 1) Responsive to communication(s) filed on 17 Ju  | ine 2010.   |  |              |  |  |  |
| ·- · · · · · · · · · · · · · · · · · ·  | action is non-final.  |  |              |  |  |  |
| 3) Since this application is in condition for allowar   | nce except for formal matters, pro  | secution as to the   | e merits is  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |   |  |              |  |  |  |
| Disposition of Claims   |   |  |              |  |  |  |
| ` <u> </u>  | application   |  |              |  |  |  |
| 4) Claim(s) 11-17 and 19-32 is/are pending in the application.  |   |  |              |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.   |   |  |              |  |  |  |
| 6) Claim(s) is/are rejected.  |   |  |              |  |  |  |
| 7) Claim(s) is/are objected to.   |   |  |              |  |  |  |
| 8) Claim(s) 11-17, 19-32 are subject to restriction   | and/or election requirement   |  |              |  |  |  |
| ,,  | and of oldstorroquioment.   |  |              |  |  |  |
| Application Papers  |   |  |              |  |  |  |
| 9)☐ The specification is objected to by the Examine   |   |  |              |  |  |  |
| 10) The drawing(s) filed on is/are: a) acce   | epted or b) dobjected to by the I   | Examiner.  |              |  |  |  |
| Applicant may not request that any objection to the   | drawing(s) be held in abeyance. See   | 37 CFR 1.85(a).  |              |  |  |  |
| Replacement drawing sheet(s) including the correct  | ion is required if the drawing(s) is obj  | ected to. See 37 C   | FR 1.121(d). |  |  |  |
| 11)☐ The oath or declaration is objected to by the Ex   | aminer. Note the attached Office  | Action or form P   | TO-152.      |  |  |  |
| Priority under 35 U.S.C. § 119  |   |  |              |  |  |  |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  | priority under 35 U.S.C. § 119(a)   | -(d) or (f).   |              |  |  |  |
| 1.☐ Certified copies of the priority documents have been received.  |   |  |              |  |  |  |
| Certified copies of the priority documents have been received.      Certified copies of the priority documents have been received in Application No.  |   |  |              |  |  |  |
| Copies of the certified copies of the prior   |   |  | Stane        |  |  |  |
| application from the International Bureau   | •   | o in tino riditoria.   | Olago        |  |  |  |
| * See the attached detailed Office action for a list  |   | d  |              |  |  |  |
|   |   |  |              |  |  |  |
|   |   |  |              |  |  |  |
| Attachment(s)   |   |  |              |  |  |  |
| Notice of References Cited (PTO-892)  | 4) Interview Summary  | (PTO-413)  |              |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Da   | ite  |              |  |  |  |
| 2) Information Single power Class country (ECTS) CS(SE)   | <ol> <li>Nation of Informal F</li> </ol>  | atert Abblication  |              |  |  |  |

| Notice of References Cited (PTO-892)                     | 4) Interview Summary (PTO-413)           |   |
|--|--|---|
| Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date                    |   |
| 3) Information Disclosure Statement(s) (PTO/SB/08)       | 5) Notice of Informal Patent Application | _ |
| Paper No(s)/Mail Date                                    | 6) Other: .                              |   |

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#### DETAILED ACTION

Applicants election without traverse of Group 4, claims 11-17, and 19-32 is noted. A presponse to applicants comments regarding restriction will be provided in the first substantive action on the merits. However, applicants have argued that at least claims 17, 23, 26 and 27 should be rejoined, as they claim reperfused-ischemic disorders. If it is applicants contention that these disorders are species of the elected "reperfusion disorder in ischemic disease", applicants are required to elect a single reperfusion disorder in ischemic disease as recited in the above mentioned claims. Otherwise such species may be considered outside the scope of the elected species and withdrawn. Furthermore, it is also noted that claims 30-32 were newly added in response to the restriction requirement, which recite multiple patentably distinct species. Applicants are required to elect a single species as discussed below.

### Election/Restrictions

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species of polyhydroxylamines, species of cyclodextrin-based dendritic macromolecules, species of 1,3-dipolar addition polymers, and species of carbohydrate-containing biodegradable polyesters.

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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: at least claims 11-15 read on the elected condition.

# REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

### WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James (Doug) Schultz, PhD whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James (Doug) Schultz, PhD/ Primary Examiner, Art Unit 1633